

Abstract

Background: Mindfulness-based therapy has been found to be an efficacious treatment for a range of mental and physical health conditions. There are increasing efforts to deliver benefits of mindfulness through less intensive/more accessible modalities but whether this efficacy holds in lower-intensity forms is unknown. This paper reviews the effectiveness of mindfulness delivered in a self-help manner for reducing symptoms of anxiety, depression and stress.

Methods: We conducted a systematic search on a number of databases. Data were analysed with primary outcome measures of depression, anxiety and stress, and a secondary outcome of mindfulness. Sub-group analyses were completed for active control versus passive control.

Findings: Analyses revealed statistically significant differences for primary and secondary outcomes, favouring the intervention group. Sub-group analyses were conducted for depression and anxiety (passive control) and depression (active control) and showed no significant differences.

Discussion: There is support for the use of mindfulness in a self-help format, although there are relatively few studies and sample sizes are generally small. The high heterogeneity reduces the potential impact of these findings as well as mixed ratings for risk of bias within studies. Limitations of this review and implications for future research are discussed.

Keywords: Mindfulness, Self-Help, Meta-Analysis, RCTs

Introduction

The term 'self-help' has been variously defined (Cavanagh, Strauss, Forder, & Jones, 2014; Lewis et al., 2003), and is often used interchangeably with 'self-management', 'self-care', 'self-instruction' or 'psychoeducational' interventions (Lewis et al., 2003). Cuijpers' (1997) definition focusses on the individual helping themselves without therapist input, and separates psychoeducation from 'self-help', in that providing information alone is not enough; there must be a more structured approach involving skills-based teaching, or techniques that allow the individual to make active changes. Furthermore, the extent to which self-administered interventions involve facilitation from a practitioner vary greatly, from those which are 'purely self-help' to those involving differing levels of practitioner support, or guided self-help. Research has sought to categorise treatments based on the amount of therapy contact (Glasgow & Rosen, 1978), and many systematic reviews have since categorised self-help treatments based on these recommendations (e.g., Cavanagh et al., 2014; Newman, Erickson, Przeworski, & Dzus, 2003; Newman, Szkodny, Llera, & Przeworski, 2011), including both non-guided self-help (therapist contact for assessment only) alongside guided self-help (less than 1.5 hours therapist time).

There is a growing amount of research examining the use of self-help psychological interventions, both in psychiatric disorders, and with reducing general psychological distress in sub-clinical populations. Given the current climate of austerity across much of the Western world, it is unsurprising that self-help interventions feature as a first line of treatment for a number of psychiatric disorders including mild-to-moderate depression and anxiety (National Institute for Health and Care Excellence (NICE), 2009, 2011). Using self-help treatment as the first line of intervention within a stepped care model (NICE 2009) allows for widening access to psychological therapies and follows recommendations for providing effective interventions in the least intrusive manner (Andersson et al., 2005). This is especially pertinent for mild to moderate difficulties, or indeed for non-clinical populations that may require some level of need (e.g., stress in the workplace). Bower and Gilbody's (2005) review examining a stepped care model for psychological therapies, recommended further research into the cost-effectiveness and acceptability of self-help or minimal contact therapies before these can be adopted across the board. Interestingly, a recent meta-analysis on minimal contact therapies and their efficacy, cost-effectiveness and acceptability found that none of the 31 included randomised controlled trials (RCTs) reported data on cost-effectiveness, or acceptability to patients (Lewis, Pearce, & Bisson, 2012), although two non-RCTs have estimated savings of \$540-\$630 per client when compared with standard individual cognitive behavioural therapy (CBT) (Newman, Consoli, & Taylor, 1999; Newman, Kenardy, Herman, & Taylor, 1997). The Lewis et al. (2012) review also showed overall effectiveness of self-help when compared to a waiting list control across all conditions, but showed that face-to-face individual therapy was more effective than use of self-help. However, other research has found that there is no difference in effectiveness of guided self-help compared with face-to-face treatment for treatment of depression and anxiety (Cuijpers, Smit, Bohlmeijer, Hollon, & Andersson, 2010); indeed, there was a small effect favouring guided self-help, although this was not statistically significant. However, the authors highlight that participants included in these studies consented to randomisation to either self-help or face-to-face (and there were no significant differences between the two intervention modalities in terms of drop-out rates), which may not be representative for all those

seeking help with anxiety or depression (i.e. not all those seeking help for anxiety and depression would accept a 50:50 chance of receiving a self-help treatment). It would be interesting to further investigate any participants who were invited but did not consent, to highlight any differences (e.g. levels of distress), and this would answer an important question surrounding for whom is self-help most appropriate or acceptable. Furthermore, systematic reviews of non-guided self-help have found this to be effective for reducing anxiety (Lewis et al., 2012) and depression (Cuijpers et al., 2011), although effect sizes for this non-guided self-help were lower than for guided self-help treatments.

Many systematic reviews of self-help include both these interventions with some (but minimal) therapist contact, alongside those that are purely self-help (e.g. Cavanagh et al., 2014). The NICE guidance for depression uses the term 'self-help' but refers to guided self-help, with the use of weekly telephone contact with a therapist (NICE, 2009). Whilst this is still deemed the first stage of the stepped care model, it is possible that therapies with no contact could be clinically effective (e.g. Cuijpers et al., 2011; Lewis et al., 2012), and relatively cost-effective. Therefore, given the differences between guided and non-guided self-help (both in terms of therapist contact time and the effect sizes from research), for the purpose of this review we focus only on those studies without therapist contact, except input for assessment only.

Mindfulness is part of the 'third wave' of CBT interventions (Kahl, Winter, & Schweiger, 2012). Although difficult to define, Bishop and colleagues (Bishop et al., 2004), based on an expert consensus approach on the elements of mindfulness, identified two components: (1) sustained attention to present experience allowing for increased recognition of mental events, and (2) an attitude of openness, curiosity, and acceptance towards these experiences in the present moment.

There are two predominantly used mindfulness based interventions: Mindfulness Based Stress Reduction (MBSR; Kabat-Zinn, 1990) and Mindfulness Based Cognitive Therapy (MBCT; Segal, Williams, & Teasdale, 2002). MBCT was developed by integrating MBSR with some aspects of traditional CBT for depression. Both MBSR and MBCT interventions were developed as 8-session, group based interventions. Mindfulness interventions in this group format have been found to be effective across a number of conditions, e.g. depression and anxiety (Hofmann, Sawyer, Witt, & Oh, 2010), but also for 'healthy' participants in coping with stress (Chiesa & Serretti, 2009). Indeed, a large-scale systematic review and meta-analysis found that mindfulness-based treatments were significantly more effective than no intervention as well as other psychological interventions, although CBT was found to be equally as effective (Khouri et al., 2013).

Many of the self-help treatments evaluated have focussed on CBT interventions. However, a recent meta-analysis (Cavanagh et al., 2014) focussed on mindfulness-based self-help interventions and showed statistically significantly decreased symptoms of anxiety and depression. This meta-analysis demonstrated the use of these 'third wave' interventions to be delivered in a self-help format. However, the review did not separate those interventions which were pure mindfulness/acceptance-based, from integrative approaches (e.g., CBT with mindfulness). The authors therefore conclude that it is difficult to highlight what the 'active ingredient' of the self-help intervention is; it could be that the CBT components

are effective in a self-help format, rather than the mindfulness. Furthermore, this review focussed on both mindfulness intervention and acceptance-based intervention (e.g., Acceptance and Commitment Therapy [ACT]; Hayes, 2004). Whilst there is an overlap between these two interventions, there are distinct differences. As the Cavanagh et al. review combined both approaches; the differences in effectiveness could be dependent on the chosen intervention.

To address this concern, this review focussed specifically on mindfulness. We used the Bishop et al. (2004) two-component operationalization of mindfulness, and self-help was defined as any intervention that was completed without therapist input (except for assessment, which can be therapist led or completed in a self-report manner). The aims of this review were to evaluate the effectiveness of mindfulness self-help interventions for (1) reducing psychological distress (depression, anxiety, and stress; primary outcomes) and (2) increasing mindfulness (as the putative target process/mechanism of action; secondary outcome).

Method

Literature search

We systematically searched the following electronic bibliographic databases from their inception to 01/07/2016 (last search): Allied and Complementary Medicine Database (AMED), Cumulative Index to Nursing and Allied Health (CINAHL), EMBASE, MEDLINE, and PsycINFO. These databases were selected to give a range of results with foci beyond western publications and across disciplines (e.g. nursing, allied health professionals). A search strategy was created for MEDLINE and amended for each database (see Appendix A). Grey literature was also searched using GreyNet and the British Library ETHoS databases. The search strategy was developed by the lead author in consultation with the co-authors, and was based on the following inclusion/exclusion criteria: we included RCTs of 'pure' mindfulness interventions (i.e., not a mindfulness intervention as part of ACT or Dialectical Behavioural Therapy (DBT)), delivered in a self-help format (non-guided, see earlier definition), for adults, which included an outcome assessing depression, anxiety or stress. We excluded studies if they were a re-analysis or sub-group analysis of primary studies, or were a sub-study of an included trial.

The lead author screened the papers using the title and abstract. In cases where the abstract provided insufficient detail to determine inclusion, full papers were accessed. If there was any uncertainty regarding the inclusion or exclusion of a paper, co-authors were consulted.

Data extraction & analysis

Descriptive data were extracted, and means, standard deviations (SD), and sample size (n) were entered into Review Manager (RevMan) version 5.3 software (The Cochrane Collaboration, 2014) to test for overall effects and calculate estimated effect sizes using Hedges *adjusted g*. Random effects models were chosen due to the nature of the samples within studies (different populations), and the varying modalities of the interventions. For trials with three arms, these were scrutinised on an individual basis following guidance from the Cochrane Collaboration (Higgins & Green, 2011). If

there were two self-help intervention arms, the intervention with the least therapist input was selected, in keeping with criteria for a non-guided intervention. Where multiple measures were used for a particular outcome, complete measures were used over sub-tests. If there were multiple complete measures or sub-tests, we arrived at a consensus as to which to use before analysis, to minimise any bias. The primary outcomes were depression, anxiety and stress with a secondary (process) outcome of mindfulness. The data were analysed initially across all studies for the primary and secondary outcomes. We then conducted a secondary analysis with the studies split into those with 'active' and 'passive' controls, using criteria from previous trials (Clare & Woods, 2004; Huntley, Gould, Liu, Smith, & Howard, 2015), which defined passive controls as waitlist or treatment as usual or usual care, and active controls as any activity or intervention that was delivered as part of the trial which would not form part of usual care. This secondary analysis helped to determine whether self-help mindfulness was (1) better than doing nothing (passive control) and/or (2) better than doing something else (active control). Sensitivity analyses were completed to remove any studies with a high risk of bias rating, to investigate any effect these may have had on effect sizes and/or statistical significance and/or heterogeneity.

Assessment of trial quality

A risk of bias tool (Higgins et al., 2011) was used to assess study quality in five areas (sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data and selective outcome reporting) in line with guidance from the Cochrane Collaboration (Higgins et al. 2011). The lead author completed this and the second author independently assessed 30% of the studies (selected at random); there was perfect agreement between the two appraising authors.

Dealing with missing data

Where data were not available or unclear in papers, we contacted the corresponding author of the studies in question for further information. We assessed rates of attrition and missing data from included studies and explored how these may have affected the results of studies. We rated studies as high risk of bias if they had a post-randomisation attrition rate of 30% or more (even if an intention-to-treat analysis was used).

Assessment of Heterogeneity

We statistically assessed heterogeneity using the I^2 statistic (Higgins & Green, 2011; Huedo-Medina, Sánchez-Meca, Marín-Martínez, & Botella, 2006). If the I^2 statistic for an outcome was $\geq 50\%$, we further scrutinised the contributing (pooled) studies to explore reasons for heterogeneity.

Findings

Description of included studies

Ten studies were included in this review with 887 participants. See Figure A for the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta- Analyses;

Moher, Liberati, Tetzlaff, & Altman, 2009) diagram. The studies were from Europe (5 studies: Boettcher et al., 2014; Cavanagh et al., 2013; Cludius et al., 2015; Lever Taylor, Strauss, Cavanagh, & Jones, 2014; Moritz et al., 2015), USA (2 studies: Morledge et al., 2013; Wimberley, Mintz, & Suh, 2016), Australia (2 studies: Gluck & Maercker, 2011; Warnecke, Quinn, Ogden, Towle, & Nelson, 2011) and 1 recruiting across 11 countries from Europe, USA, Australia and Singapore (Howells, Ivtzan, & Eiroa-Orosa, 2016). Only three studies used a sample with a specific diagnosis (Boettcher et al., 2014, anxiety; Moritz et al., 2015, psychosis; Cludius et al., 2015, OCD). Two studies excluded those with a diagnosis of psychosis (Gluck & Maercker, 2011; Morledge et al., 2013). See Table 1 for characteristics of included studies.

Four studies used a bibliotherapy intervention (Cludius et al., 2015; Lever Taylor et al., 2014; Moritz et al., 2015; Wimberley et al., 2016) with three of these studies using an audio CD alongside this (Cludius et al., 2015; Lever Taylor et al., 2014; Moritz et al., 2015). The Cludius et al. (2015) and Moritz et al. (2015) studies recruited participants centrally and assigned them to either study by diagnosis (i.e., those with a psychosis diagnosis were part of the Moritz et al. 2015 trial and those with an OCD diagnosis part of the Cludius et al. 2015 trial), therefore their methods are very similar. Four studies used an internet-based intervention (Boettcher et al., 2014; Cavanagh et al., 2013; Gluck & Maercker, 2011; Morledge et al., 2013). One study (Howells et al., 2016) used a smartphone application, and one study used a CD alongside a daily diary (Warnecke et al., 2011). Interventions ranged in length from 10 days (Howells et al., 2016) to 8 weeks (Boettcher et al., 2014; Lever Taylor et al., 2014; Morledge et al., 2013; Warnecke et al., 2011). One intervention, based on an audio CD, specified that participants were asked to complete 30 minutes per day of guided practice (Warnecke et al., 2011) and another specified 6 days per week of internet based training (Gluck & Maercker, 2011). Little to no details were given by any of the included studies regarding the actual mindfulness techniques included or practiced.

One study (Morledge et al., 2013) was a three-arm trial: self-help intervention, self-help with a message board, and a no intervention control. For the meta-analysis, the self-help intervention *without* the message board was used, as the arm with the message board was deemed to be 'guided self-help'. Four studies had a waitlist control (Cavanagh et al., 2013; Gluck & Maercker, 2011; Lever Taylor et al., 2014; Wimberley et al., 2016), one study (Warnecke et al., 2011) used a 'usual care' control group, another (Morledge et al., 2013) used a 'no intervention' control, and four studies (Boettcher et al., 2014; Cludius et al., 2015; Howells et al., 2016; Moritz et al., 2015) used 'active' control groups: a 'list-making smartphone application' (Howells et al., 2016), an online discussion forum (Boettcher et al., 2014), and a progressive muscle relaxation intervention (Cludius et al., 2015; Moritz et al., 2015).

Psychological distress was most commonly examined in terms of depression; seven studies included measures of depression, with the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977) used most commonly (Cludius et al., 2015; Howells et al., 2016; Moritz et al., 2015). Six of the included papers assessed stress, with the Perceived Stress Scale (PSS; Cohen, Kamarck, & Mermelstein, 1983) as the most used measure (Cavanagh et al., 2013; Morledge et al., 2013; Warnecke et al., 2011; Wimberley et al., 2016). Four studies assessed participants' anxiety, with two of these using a form of the Depression Anxiety and Stress Scale (DASS; Lovibond & Lovibond, 1995) anxiety subscale (Lever Taylor et al., 2014; Warnecke et

al., 2011). Mindfulness was assessed in five studies, with the most commonly used measure being the Five Facet Mindfulness Questionnaire (FFMQ; (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006) (Cavanagh et al., 2013; Lever Taylor et al., 2014; Wimberley et al., 2016)).

Risk of bias of included studies

Studies were generally rated as unclear or low risk of bias with only two studies rated as having a high risk of bias on one factor (see Appendix B for the risk of bias per study, with support for judgements in Appendix C). Risk of bias per outcome summaries are presented with the forest plots. We assessed Gluck and Maercker (2011) to have a high risk of bias on random sequence generation as this was completed on an odd-even allocation, deemed 'quasi randomisation' according to the Cochrane Collaboration guidelines (Higgins & Green, 2011) and could potentially be a source of bias. We assessed Morledge et al. (2013) to have a high risk of bias for attrition. The attrition rate was high (ranging from 41% to 67%), and the authors described completing analyses on "available data" and there was no clarification of how missing data were dealt with.

The risk of bias due to allocation concealment was unclear in all but one study (Warnecke et al., 2011), where the authors specified that both intervention and control participant packs were prepared centrally and looked identical. Blinding of participants and personnel was also generally unclear. Due to the nature of the intervention, it is not always possible for participants to be blind, however, for those that had an active control group, this may be possible. However, in all studies there was no reported contact between researchers and participants as part of the intervention (these were delivered in a self-help format, without therapist contact), thus rendering the bias unclear; if the intervention was therapist led, this would suggest a higher risk of bias, however, due to the nature of the intervention delivery, the associated risk of bias is unclear. All studies were deemed low risk of bias for blinding of outcomes assessors (outcomes were self-report either online or via post in all studies) and for selective reporting.

Statistical Analyses

Primary analysis

Figure B shows the forest plots for the primary and secondary outcomes for all included studies. These show significant effects for all outcomes for the pooled studies. Note the direction of the graph is opposite for the primary outcomes as compared with mindfulness. This is due to the differential directionality of desired outcomes: for mindfulness measures, the targeted direction of change was an increase in scores (indicating greater mindfulness); conversely, for depression, anxiety, and stress measures, the targeted direction of change was a decrease in scores (indicating symptom reduction).

B.1: Depression: Seven studies (Boettcher et al., 2014; Cavanagh et al., 2013; Cludius et al., 2015; Howells et al., 2016; Lever Taylor et al., 2014; Moritz et al., 2015; Warnecke et al., 2011) included measures of depression, although one study (Cavanagh et al., 2013) is not included in this analysis as the measure used gave

combined scores for depression and anxiety; depression sub-scores were requested but not received from authors. The total number of participants included in this analysis was 521, with 253 in the intervention and 268 in the control condition. We found a statistically significant difference between the intervention and control group ($z(5) = 2.74, p = .006$), with a small effect size ($g = 0.32$, 95% CI -0.56 to -0.09), favouring the intervention group.

B.2: Anxiety: Four studies (Boettcher et al., 2014; Cavanagh et al., 2013; Lever Taylor et al., 2014; Warnecke et al., 2011) included measures of anxiety, although one study (Cavanagh et al., 2013) is not included in this analysis as the measure used gave combined scores for depression and anxiety; anxiety sub-scores were requested but not received from authors. The total number of participants included in this analysis was 226, with 109 in the intervention group and 117 in the control group. We found a statistically significant difference between the intervention and control group ($z(2) = 2.06, p = .04$), with a medium effect size ($g = 0.55$, 95% CI -1.07 to -0.03) favouring the intervention group.

B.3: Stress: Six studies (Cavanagh et al., 2013; Gluck & Maercker, 2011; Lever Taylor et al., 2014; Morledge et al., 2013; Warnecke et al., 2011) included measures of stress. The total number of participants included in this analysis was 543, with 247 in the intervention group and 296 in the control group. We found a statistically significant difference between the intervention and control group ($z(5) = 3.94, p < .001$), with a small effect size ($g = 0.37$, 95% CI -0.55 to -0.15) favouring the intervention group. Sensitivity analyses to remove the two studies which were rated as having a high risk of bias (on one aspect) did not affect the significance or direction of effect found, but increased the effect size to a moderate effect size ($g = 0.51$, 95% CI -0.75 to -0.28).

B.4: Mindfulness: Five studies (Cavanagh et al., 2013; Gluck & Maercker, 2011; Lever Taylor et al., 2014; Morledge et al., 2013; Wimberley et al., 2016) included measures of mindfulness. The total number of participants in this analysis was 487, with 223 in the intervention group and 264 in the control group. We found a statistically significant difference between the intervention and control group ($z(4) = 2.46, p = .01$) with a small to medium effect size of ($g = 0.47$, 95% CI 0.09 to 0.84), favouring the intervention group. Sensitivity analyses to remove the two studies rated as having a high risk of bias on one aspect did not affect the significance or direction of effect found, but increased the effect size to a moderate to large effect size ($g = 0.70$, 95% CI 0.25 to 1.15).

Secondary analysis

Studies with passive controls

Figure C shows the analyses for outcomes with studies that had a passive control group. Subgroup analyses are only presented for depression and anxiety outcomes, as all the studies included in the stress and mindfulness analyses above were studies with passive control groups, therefore, there is no change from those presented in Figure B.3 and B.4.

C.1: Depression: Three studies had a passive control group and measured depression (Cavanagh et al., 2013; Lever Taylor et al., 2014; Warnecke et al., 2011), although as

above the Cavanagh et al. (2013) data were not available and therefore not included in the analysis. The total number of participants included in this analysis was 135, with 64 in the intervention group and 71 in the control group. We found no statistically significant difference between intervention and control, ($z(1) = 1.96$, $p = .05$).

C.2: *Anxiety*: Again, three studies had a passive control group and measured anxiety (Cavanagh et al., 2013; Lever Taylor et al., 2014; Warnecke et al., 2011), but the Cavanagh et al. (2013) was not included as the data were not available. The total number of participants in this analysis was 135, with 64 in the intervention group and 71 in the control group. No statistically significant difference was found between the intervention and control, ($z(1) = 1.25$, $p = .21$).

Studies with active controls

Figure D shows the analyses for those studies that had an active control group. Only four studies had an active control, and none of these studies included measures of stress, or mindfulness. Only one study (Boettcher et al., 2014) included a measure of anxiety, and therefore a meta-analysis was not possible. This study found a significant difference between the intervention and control, favouring the intervention ($p = .002$) showing a large effect size ($g = 0.76$, 95% CI 0.42 to -1.09).

D.1: *Depression*: Four studies (Boettcher et al., 2014; Cludius et al., 2015; Howells et al., 2016; Moritz et al., 2015) had an active control group and included measures of depression. The total number of participants included in this analysis was 386, with 189 in the intervention group and 197 in the control group. No statistically significant difference was found between intervention and control group, ($z(3) = 1.88$, $p = .06$).

Heterogeneity

As can be seen from the forest plots, two analyses had an I^2 statistic that was significant at $\geq 50\%$ (outcomes: B.2 [all studies, anxiety] & B.4 [all studies, mindfulness]), and two others showed an I^2 statistic of above 50% (considered moderate heterogeneity; Higgins & Green, 2011) which was not significant (outcomes: C.2 [passive control, anxiety] & D.1 [active control, depression]). As the outcomes are different across the different comparisons, it is unlikely that this heterogeneity is due to varying outcome measures. There were, however, some differences between studies in terms of their participants and intervention modalities and contents. Indeed, there is little to no information provided by authors of studies about the actual techniques used in the interventions; some may have focussed on body scan techniques whereas others more on mindfulness in daily life, or a mix of techniques. This is similar for the amount of daily practice in each intervention. Inclusion into this meta-analysis was not specific to any diagnosis or population group; therefore, there were variances between the participants included in each trial. Furthermore, there are differences in the mode in which the intervention it delivered; some interventions were delivered through bibliotherapy, others using online or computer based interventions, and some using audio CDs. There is also variability in the length of the interventions investigated. Given that mindfulness is seen as a 'complex intervention' (defined by the Medical Research Council (MRC) as intervention with several interacting components (MRC; Moore et al., 2015)), we would expect some variations in delivery. However, given the basic principles underlying each intervention are consistent across

studies, it is valid to combine the studies for the purpose of a meta-analysis. Results should be viewed in light of these findings and taken to answer a more scoping question in relation to effectiveness of mindfulness in a self-help format, with further studies necessary to highlight differences in effectiveness in specific populations or with a particular modality. Further analyses on specific populations and for each individual intervention would likely give a lower I^2 , which would reduce the potential impact this heterogeneity may have on effect size estimates.

Discussion

This review highlighted that, whilst there are few studies investigating the use of mindfulness in a self-help format, there is a clear recent growth (all included studies were published within the past 5 years); moreover, the evidence to date is promising and invites further examination. Indeed, when all studies were pooled, the meta-analyses revealed significant and favourable results for both the primary and secondary outcomes of interest: demonstrating preliminary support for the efficacy of mindfulness self-help interventions in reducing psychological distress, and improving mindfulness performance. This is consistent with the findings from the Cavanagh et al. (2014) review. Interestingly, sub-group analyses for those studies with either active or passive controls found no statistically significant effects for anxiety and depression (sub-analyses were not possible for stress or mindfulness, as all included studies for these measures had a passive control). Whilst not unexpected, those studies that assessed stress were also based on samples that included healthy populations (most were mixed samples; i.e., anyone could enrol, although some studies excluded those already in therapy or with 'significant psychological distress'), which may explain why these studies did not include an active control group. The absence of significant effects within subgroup analyses for depression and anxiety outcomes may be related to the small sample sizes and few studies included within these analyses. In support of this notion, it was notable that the effect sizes for the (statistically non-significant) depression sub-analyses were of similar magnitude to the effect size observed in the (statistically significant) pooled analysis – i.e., the subgroup analyses were not adequately powered to detect the (relatively small) effect size for depression. Taken together, results supported the use of pooled analyses and suggest that there is an overall effect favouring mindfulness (irrespective of the comparison group) – albeit one of small-to-moderate magnitude. This gives preliminary evidence to suggest the clinical utility of these interventions, especially as a first-line intervention and in sub-clinical populations, e.g. stress. Furthermore, effect size estimates increased when studies of lower quality were excluded (in sensitivity analyses), indicating that larger effects may be observable with more robust research designs.

Whilst the secondary analyses focussed on the active vs. passive control split, as discussed above, differences in control group were often conflated with differences in the sampled populations (clinical vs. non-clinical/'healthy'; although one of the studies with an active control did include 'healthy' participants). Given that heterogeneity was high for a number of analyses, there were numerous ways in which to sub-group the data (and even when the sub-group analyses were completed, there was significant heterogeneity across outcomes, suggesting more differences between studies were not controlled for). As we highlighted in the introduction, there is a large body of evidence to support self-help treatments, but relatively little to pinpoint for which populations, or level of distress, self-help is most appropriate (and differences

in population or distress-severity may have contributed to high heterogeneity). In the included studies, the potential moderating role of pre-intervention distress levels is not examined; for example, do results differ for those with higher versus lower levels of anxiety or depression at intake? Whilst this would be consistent with NICE (2009) guidance for use of self-help in mild to moderate difficulties, we do not know if this is the case for mindfulness and therefore it is important to highlight any moderating factors in terms of individual differences in responsiveness to the intervention, to inform clinical decisions around allocation to interventions (e.g. stepped care, or cluster-based allocations).

The use of 'symptom reduction' measures as outcomes for mindfulness may also be inappropriate. As can be seen from the mechanisms of change described by Segal, Teasdale and Williams (2004), the aims of mindfulness programmes are not to reduce feelings of depression, anxiety, or stress. The mindfulness programmes are designed to change the way in which an individual might view those thoughts and feelings: as temporary automatic events, rather than static and factual truths. Therefore, it might be more appropriate to focus on the *impact* these symptoms might have on an individual, rather than their presence. Therefore, outcomes such as quality of life may be more suited to judge the effectiveness of such interventions.

Significant differences between intervention and control on scores of mindfulness provide an indication of the internal validity of the included studies, and some reassurance that heterogeneity is unlikely to be due to differences in the mindfulness content of included studies. As an outcome, increases in mindfulness may not be meaningful for the participants themselves. Therefore, this should be viewed as a process variable, giving insight into possible mechanisms of change, rather than an outcome per se. Clinically, this begs the question of the aims of the mindfulness intervention. As discussed above, measuring distress might not be appropriate, and if measures of mindfulness give little indication of the meaningfulness or function of this for clients, then it is important to first understand the aims of mindfulness interventions. Clinically, it would be important to assess the individual meaning and sequelae of increased mindfulness for each client (whether positive or negative – it may be that a client's increases in mindfulness has detrimental consequences for their lives; Lustyk et al., 2009) rather than relying on quantitative measures of symptoms/distress or use of mindfulness techniques/adopting mindfulness in daily life. Attention to the rationale for increasing mindfulness, and what this would mean and enable for the individual client, would seem to be critical: both to foster client engagement and to be able to evaluate intervention success (focussing more on whether increasing mindfulness is facilitating functional goals versus assessing mindfulness as an outcome in itself).

Given evidence showing the importance of inquiry and therapist skill in developing the process of mindfulness, it is noteworthy that this review's findings suggest that it remains possible to foster mindfulness (or at least, improvements in self-reported awareness and acceptance of present moment experiences) in the absence of therapist contact. Although both the mainstream mindfulness programmes were developed for groups, and emphasise the therapist-led and peer-to-peer inquiry process, this review suggests that therapist and peer contacts may not be essential to derive beneficial effects from mindfulness-based intervention. Although, it is important to view this in light of the samples included in these studies. MBCT was developed specifically for depression; none of the included studies had a sample with a diagnosis

of depression, although most did not exclude those participants either. Therefore, as discussed above, there may be populations for which this is a viable treatment option, whereas for other populations this might not be sufficient. Further trials are needed to get a better indication of the effectiveness of this intervention for particular populations, and perhaps an indication of when it might be most effective (e.g. following NICE guidance about a first line of treatment).

The studies themselves were predominantly completed online, which may have affected rates of attrition. Indeed, one study (Morledge et al., 2013) had a level of attrition of 67% for the control, and 41% for self-help. Whilst the authors had anticipated a higher level of attrition (given research showing higher attrition for online studies), this may give some indication of the acceptability of the intervention. Again, this may be linked to the study's sample (participants with and without a clinical diagnosis, only excluding psychosis), although other studies found lower attrition levels. Furthermore, there may have been differences between different intervention modalities in terms of engagement. For example, do participants engage more with interventions that are delivered online where they might be more interactive? The studies report few details about engagement with the intervention itself (or the daily tasks), which might give an indication of the acceptability of the intervention, and the modality. In fact, no studies included follow-up interviews with participants to obtain their views about these aspects of the intervention. Whilst participant engagement and levels of attrition may give some indication of the intervention acceptability, this may also have an economic impact. High dropout rates for face-to-face therapies can have an economic impact, however, this may not be the case for online self-help studies (given the argument that these are much cheaper than traditional face-to-face therapies). No studies included cost-effectiveness or economic analyses. Given the economic argument for self-help as a first line of treatment, which could be distributed easily and inexpensively to a large population, this was not investigated in the studies themselves. Therefore, if an economic argument is to be made for promoting self-help treatments, this must be evidenced in future trials. An additional problem with the lack of information on how participants engaged with the interventions is that intervention integrity or adherence is unclear. Available evidence suggests that, overall, being assigned to receive a mindfulness self-help intervention may have beneficial effects – and this conclusion is unlikely to be affected by attrition bias (low risk of bias in primary studies). However, without understanding how participants engaged with the intervention, and how this differed from the experience of those in comparison conditions, it is difficult to draw conclusions about processes underlying any beneficial effects – and whether such effects can be attributed to the intervention being used as intended. This is a problem for self-help interventions more broadly, but an important one to resolve (e.g., through analysis of remotely-collected process data on how individual participants are using intervention resources) in order to make conclusive statements about intervention effects and identify ways of optimising interventions. It may be that the aggregate effects of self-help interventions are being suppressed by low levels of adherence; which, once understood, could be improved.

Given the NICE guidance (2009) for depression and anxiety cite CBT self-help as first line treatments, it is important to compare emerging mindfulness interventions with alternatives that are currently best-supported within evidence-based practice guidelines. Yet, there are no head-to-head trials comparing mindfulness self-help to CBT self-help. One study (Ly et al., 2014) was excluded from this review which

compared mindfulness self-help to behavioural activation; this was excluded as the mindfulness self-help was a guided programme. Whilst it is useful to know that there is evidence to support the use of mindfulness in a self-help format, the pertinent question is whether this is more or less clinically and cost-effective than CBT self-help programmes which are currently offered within usual clinical care. Indeed, this review would suggest preliminary evidence for the use of mindfulness self-help, especially in populations with sub-clinical difficulties (e.g., stress) that are currently less like to receive treatment in the UK stepped care model. Furthermore, given the use of MBCT and MBSR groups within the NHS, it would be interesting to investigate whether there are any differences in terms of effectiveness for these groups against a self-help intervention. Again, one study which explored this (Nyklicek, Dijkstra, Lenders, Fonteijn, & Koolen, 2014) was excluded due to having a guided self-help.

In summary, this review offers preliminary evidence that mindfulness can be delivered in a self-help format. However, as highlighted above, there are questions yet to be answered about the impact of individual differences on its efficacy, and further research is necessary to give further insight into this, alongside some evidence to support the economic argument for use of self-help therapies. The comprehensibility of existing research is limited somewhat by deficits in reporting (particularly with respect to the content of 'mindfulness' interventions), which may obscure pertinent differences between studies: attention to clarity of reporting in future research could enable identification of important sources of conditionality (highlighting variables for researchers and clinicians to modulate when designing and implementing these interventions).

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Table 1: Characteristics of included studies

Study	Sample	n	Intervention (I), Control (C),	Intervention duration	Outcome measures			
					Depression	Anxiety	Stress	Mindfulness
Boettcher et al. 2014 (Germany)	Clinical Anxiety (assessed using SCID); excluded those with suicide ideation or severe depression (assessed using BDI-II)	91	I: Internet-based mindfulness treatment comprising 8 modules (one per week) C: Online discussion forum (active)	8 weeks	BDI-II	BAI		
Cavanagh et al. 2013 (UK)	Healthy, no exclusions	104	I: 'Learning mindfulness online' with introductory material, daily practices, daily practice frequently asked questions and daily journal C: Waitlist control (passive)	2 weeks	PHQ-4	PHQ-4	PSS	FFMQ
Cludius et al. 2015 (Germany)	Diagnosis of OCD	87	I: 15-page Mindfulness manual with audio files and exercises C: 3-page Progressive muscle relaxation manual and instructional audio file (active)	6 weeks	CES-D			
Gluck & Maercker 2011 (Australia)	Healthy (excluded those with psychosis, suicide ideation or clinical level distress)	49	I: Internet-based training, 6 days per week. Two modules, one focussing on techniques and second practicing these techniques C: Waitlist control (passive)	13 days			PSQ	FMI
Howells et al. 2016 (Various countries)	Healthy, no exclusions	121	I: 'Headspace on the go' smartphone application using mindfulness techniques and daily practice C: 'Catch notes', a list making smartphone application (active)	10 days	CES-D			

Study	Sample	n	Intervention (I), Control (C),	Intervention duration	Outcome measures			
					Depression	Anxiety	Stress	Mindfulness
Lever-Taylor et al. 2014 (UK)	Healthy; excluded those in therapy or already practising mindfulness	80	I: MBCT-SH ("Mindfulness: A practical guide to finding peace in a frantic world" and CD) C: Waitlist control (passive)	8 weeks	DASS-21 (depression subscale)	DASS-21 (anxiety subscale)	DASS-21 (stress subscale)	FFMQ
Morledge et al. 2013 (USA)	Healthy and Clinical (excluding psychosis)	551	I: Internet-based Stress Management Program (ISM) I: ISM + Message board C: No intervention (passive)	8 weeks			PSS	MAAS
Moritz et al. 2015 (Germany)	Diagnosis of psychosis	90	I: 15-page Mindfulness manual with audio files and exercises C: 3-page Progressive muscle relaxation manual and instructional audio file (active)	6 weeks	CES-D			
Warnecke et al. 2011 (Australia)	Healthy (medical students); excluded those with significant psychological distress	66	I: CD guided mindfulness (30mins guided practice each day) and daily diary C: Usual care (passive)	8 weeks	DASS-10 (depression subscale)	DASS-10 (anxiety subscale)	PSS DASS-10 (stress subscale)	
Wimberley et al. 2016 (USA)	Healthy; no exclusions	63	I: Bibliotherapy 'Present Perfect' comprising of 6 parts C: Waitlist control (passive)	6 weeks			PSS	FFMQ

Measures: BAI= Beck Anxiety Inventory, BDI-II= Beck Depression Inventory-II, CES-D= Center for Epidemiologic Studies Depression Scale, FFMQ= Five Facet Mindfulness Questionnaire, FMI= Freiburg Mindfulness Inventory, MAAS= Mindfulness Attention and Awareness Scale, SAD-4= Symptoms of Anxiety and Depression index, PSS= Perceived Stress Scale, PSQ= Perceived Stress Questionnaire

Other abbreviations: SCID= Structured Clinical Interview for DSM, OCD= Obsessive Compulsive Disorder

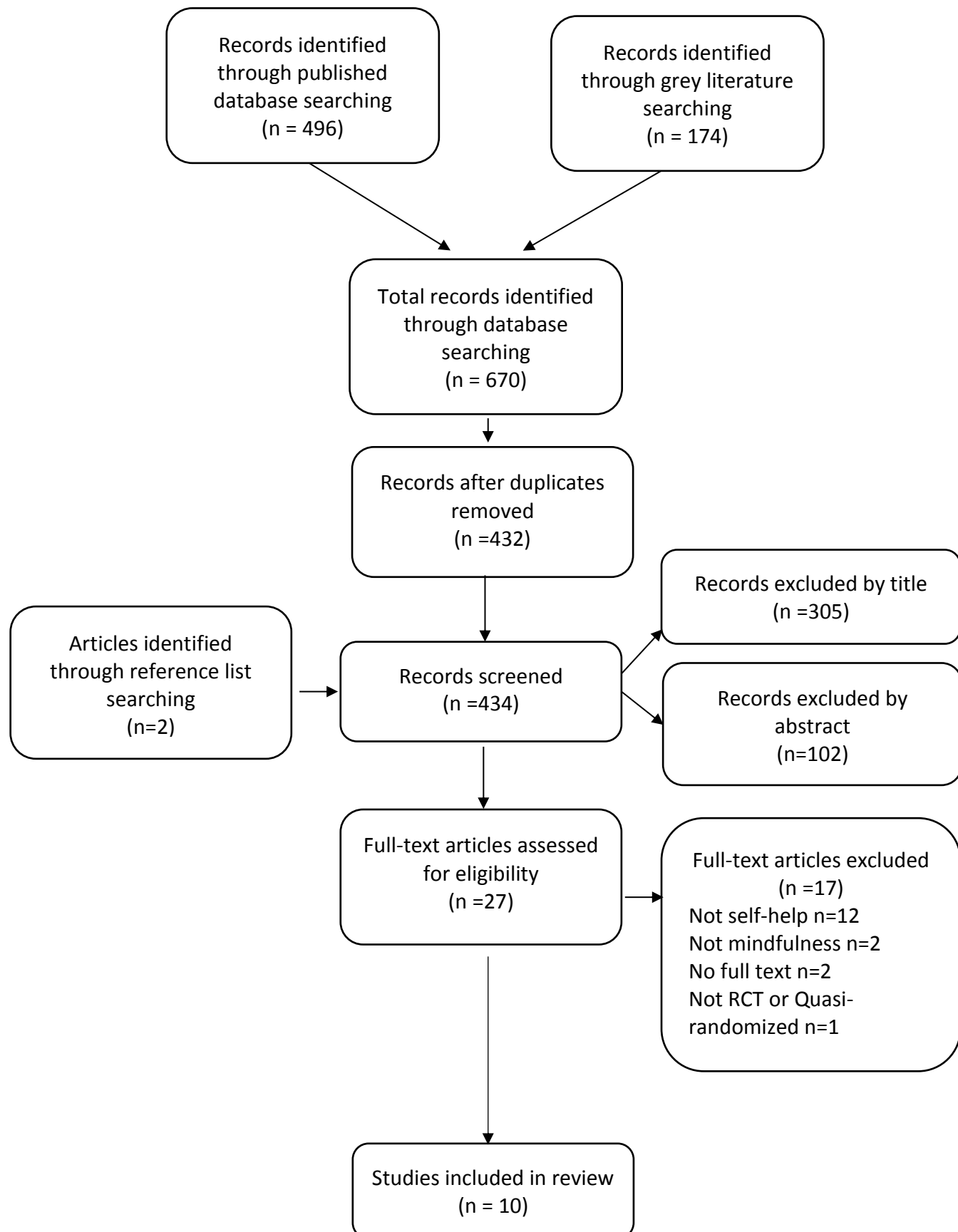
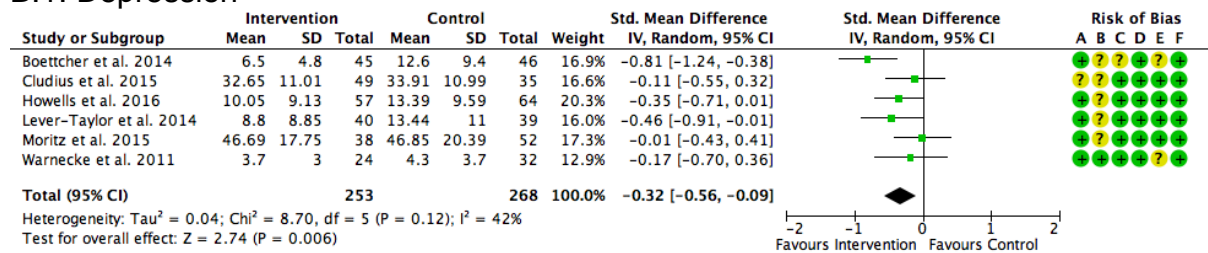
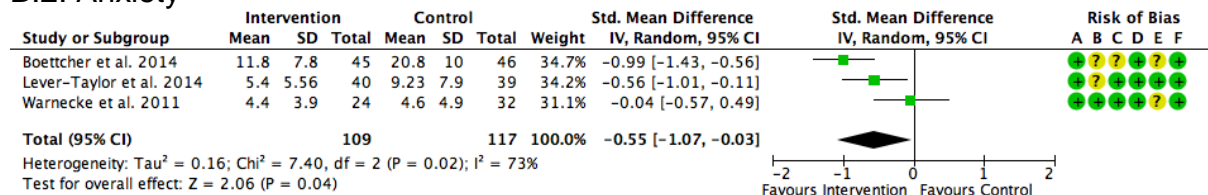
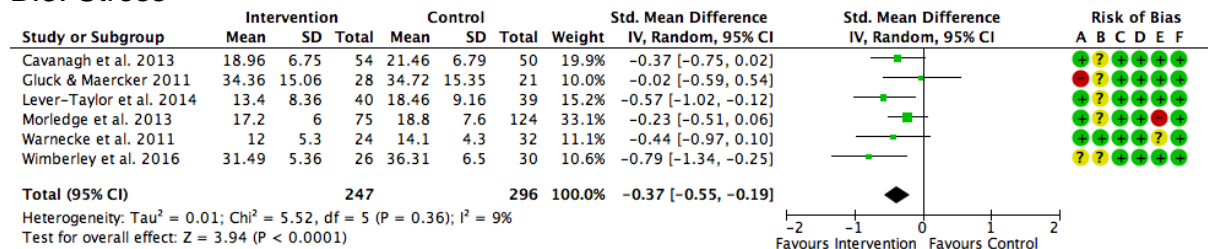
Figure A: PRISMA diagram showing the article screening process

Figure B: Forest plots showing primary analyses for the pooled studies**B.1: Depression**Risk of bias legend

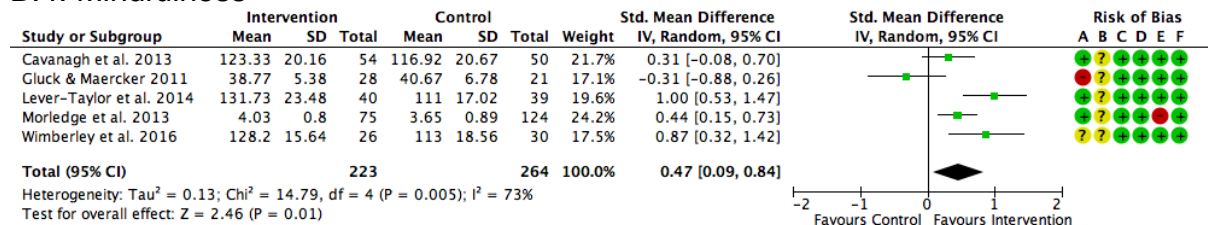
- (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias)
 (D) Blinding of outcome assessment (detection bias)
 (E) Incomplete outcome data (attrition bias)
 (F) Selective reporting (reporting bias)

B.2: AnxietyRisk of bias legend

- (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias)
 (D) Blinding of outcome assessment (detection bias)
 (E) Incomplete outcome data (attrition bias)
 (F) Selective reporting (reporting bias)

B.3: StressRisk of bias legend

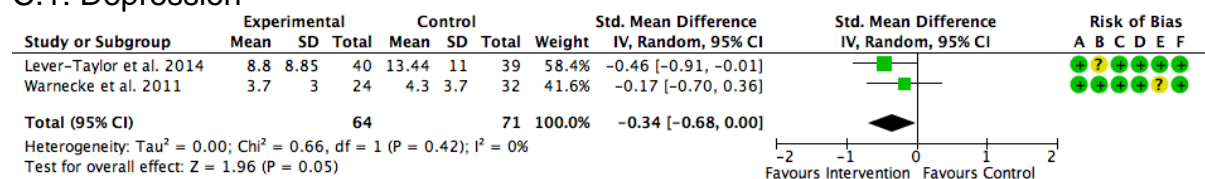
- (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias)
 (D) Blinding of outcome assessment (detection bias)
 (E) Incomplete outcome data (attrition bias)
 (F) Selective reporting (reporting bias)

B.4: MindfulnessRisk of bias legend

- (A) Random sequence generation (selection bias)
 (B) Allocation concealment (selection bias)
 (C) Blinding of participants and personnel (performance bias)
 (D) Blinding of outcome assessment (detection bias)
 (E) Incomplete outcome data (attrition bias)
 (F) Selective reporting (reporting bias)

Figure C: Forest plots showing secondary analyses for studies with a passive control group

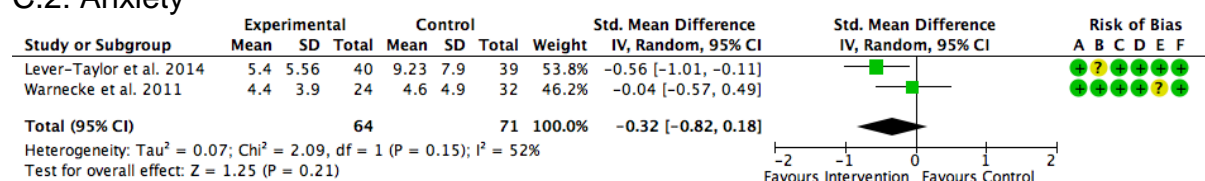
C.1: Depression



Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)

C.2: Anxiety

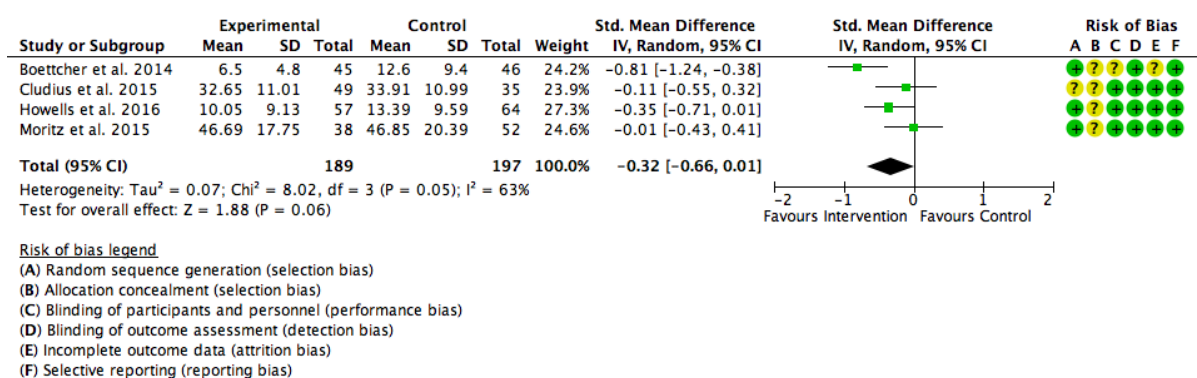


Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)

Figure D: Forest plot showing secondary analyses for studies with an active control group

D.1: Depression



Appendix A: Medline search strategy

1. mindful*.mp.
2. exp Meditation/
3. mindfulness based cognitive therapy.mp.
4. MBCT.mp.
5. mindfulness based stress reduction.mp.
6. MBSR.mp.
7. mindful*.mp.
8. Bibliotherapy.mp. or Bibliotherapy/
9. Book\$.mp. or Books/
10. self help.mp.
11. self guided.mp.
12. self instruction.mp.
13. self care.mp.
14. exp therapy, computer-assisted/
15. randomized controlled trials/
16. random allocation/ or placebos/
17. randomized controlled trial.pt.
18. clinical trial.pt.
19. controlled clinical trials.mp.
20. clinical trials.mp.
21. (random\$ or placebo\$).mp.
22. (controlled adj5 (trial\$ or stud\$)).mp.
23. (clinical\$ adj5 trial\$).mp.
24. clinical trial.mp.
25. RCT.mp.
26. 1 or 2 or 3 or 4 or 5 or 6 or 7
27. 8 or 9 or 10 or 11 or 12 or 13 or 14
28. 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25
29. 26 and 27 and 28

Appendix B- Risk of bias summary graph

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Boettcher et al. 2014	+	?	?	+	?	+
Cavanagh et al. 2013	+	?	+	+	+	+
Cludius et al. 2015	?	?	+	+	+	+
Gluck & Maercker 2011	-	?	+	+	+	+
Howells et al. 2016	+	?	+	+	+	+
Lever-Taylor et al. 2014	+	?	+	+	+	+
Moritz et al. 2015	+	?	+	+	+	+
Morledge et al. 2013	+	?	+	+	-	+
Warnecke et al. 2011	+	+	+	+	?	+
Wimberley et al. 2016	?	?	+	+	+	+

Appendix C- Risk of Bias Author Judgements

Boettcher et al. 2014

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"participants were randomly allocated to the mindfulness treatment group (MTG) or the discussion forum control group (CG) by an online true-number service independent of the investigators" (p.244)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Unclear risk	Study completed online. Authors report that CG had online discussions that were supervised by the investigators did not take active part, suggesting not blind
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Unclear risk	Low attrition
Selective reporting (reporting bias)	Low risk	No discussion of how missing data dealt with No selective reporting apparent

Cavanagh et al. 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"randomised, using a computer-generated blocked random allocation method" (p.575)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Blinding of participants not possible, study completed entirely online (except contact for technical difficulties)
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Attrition high (57.3%) but authors analysed differences between completers and non-completers, intention to treat analysis used and missing data addressed.
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Cludius et al. 2015

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No mention of how randomisation was completed
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	No mention of blinding of participants, study otherwise completed online
Blinding of outcome assessment (detection bias)	Unclear risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Per protocol analyses used, author analysed differences between completers and non-completers
Selective reporting (reporting bias)	Low risk	No selective reporting identified

Gluck & Maercker 2011

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Assignment by odd-even allocation
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Completed entirely online, no contact between participants and researchers
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Intention to treat analyses used and attrition low
Selective reporting (reporting bias)	Unclear risk	Unclear reporting on data from cross-over of waitlist control

Howells et al. 2016

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"website software randomly allocated participants to an experimental or control condition" (p.169)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Participants blind to treatment allocation and study completed entirely online
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Per protocol analyses used, researchers discuss attrition and completed analyses to highlight differences between completers and non-completers
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Lever-Taylor et al. 2014

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"A researcher independent to the research team and blind to participant details conducted randomisation by stratifying participants according to DASS-21 stress scores and applying block randomisation in blocks of four" (p. 65)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Participant not blind, completed online with automated emails, therefore no contact with researchers
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Intention to treat analyses used, one participant removed from analysis due to being an outlier on baseline assessments
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Moritz et al. 2013

Bias	Authors' judgement	Support for judgement
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Random sequence generation (selection bias)	Low risk	"Participants were randomly allocated (fully automated randomization according to date of participation)" (p.710)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment, although automatically randomised and sent relevant intervention packs
Blinding of participants and personnel (performance bias)	Low risk	Fully automated system so no contact between participants and researchers
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Per protocol and intention to treat analyses completed to see effects of attrition
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Morledge et al. 2013

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"automatically randomized (using a computer-generated list with a block size of three)" (p.138)
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Completed entirely online, no contact between researchers and participants
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	High risk	Attrition was high; 67% control, 44% for ISM+ and 41% for ISM, analysis completed on "available data" (p.140), no mention of how missing data was dealt with
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Warnecke et al. 2011

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Eligible participants were randomised centrally, using block randomisation with block sizes of two" (p.383)
Allocation concealment (selection bias)	Low risk	"Participant packs were prepared centrally. All packs contained a CD cover so that trial packs in the two arms of the study looked identical. The purpose of this was to conceal allocation." (p.383)
Blinding of participants and personnel (performance bias)	Low risk	Participant blinding not possible, intervention and measures completed online
Blinding of outcome assessment (detection bias)	Low risk	"Both the research assistant who scored and entered data and the statistician who analysed the results were blinded to group allocation." (p.383)
Incomplete outcome data (attrition bias)	Unclear risk	Intention to treat analysis reported to be used, but missing data were not inputted and were left as blank (potentially biasing data as analyses effectively on 'completer' data)
Selective reporting (reporting bias)	Low risk	No selective reporting apparent

Wimberley et al. 2016

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"randomly assigned to either the intervention group or the WLC group" No mention of how randomisation completed
Allocation concealment (selection bias)	Unclear risk	No mention of allocation concealment
Blinding of participants and personnel (performance bias)	Low risk	Completed entirely online, no contact between researchers and participants except for email reminders
Blinding of outcome assessment (detection bias)	Low risk	Outcomes completed online, without researcher contact
Incomplete outcome data (attrition bias)	Low risk	Low attrition, missing data discussed, analysis on completers only
Selective reporting (reporting bias)	Low risk	No selective reporting apparent